Exhibit D

State of California
Office of the Attorney General
XAVIER BECERRA
ATTORNEY GENERAL

March 30, 2020

Secretary Alex M. Azar II
U.S. Department of Health & Human Services
200 Independence Ave., S.W.
Washington, DC 20201

Commissioner Stephen Hahn
U.S. Food & Drug Administration
10903 New Hampshire Ave., N.W.
Silver Spring, MD 20993

Dear Secretary Azar and Commissioner Hahn:

We write to request that you increase access to reproductive healthcare, including safe and legal abortion, during this pandemic. Specifically, as the U.S. Food & Drug Administration (FDA) considers policy changes in response to the Coronavirus Disease 2019 (COVID-19) public health emergency, we urge you to waive its Risk Evaluation and Mitigation Strategy (REMS), or use FDA enforcement discretion, to allow certified prescribers to use telehealth for Mifepristone, the medication abortion prescription drug.[1] The REMS create unnecessary delays for women who need access to time-sensitive healthcare and force them to travel unnecessarily.

During this unprecedented crisis, we need to ensure that women across the country have access to critical healthcare services. Steps have already been taken in many States at the behest of the federal government to increase telehealth. Yet, the current FDA REMS create unnecessary barriers between women and abortion care, not only making it harder to find—for example, by prohibiting sale by retail or mail-order pharmacies—but also making it unappealing to prescribe. By barring the use of telehealth, the REMS force women to travel at a time when many States and the federal government are urging people to stay home to curb the spread of COVID-19. Further, in some States across the country, like Texas and Ohio, politicians are using the pandemic to further restrict women's access to care by deeming abortion "nonessential" healthcare.[2] Denying women care and forcing them to travel unnecessarily is not

[1] FDA-2020-D-1106, https://www.regulations.gov/comment?D=FDA-2020-D-1106-0018.

[2] Sabrina Tavernise, *Texas and Ohio Include Abortion as Medical Procedures That Must Be Delayed*, New York Times (March 23, 2020), https://www.nytimes.com/2020/03/23/us/coronavirus-texas-ohio-abortion.html.

only shortsighted, it is putting women across the country in harm's way. Consequently, we urge you to act immediately and remove the FDA REMS designation.

Since 2000, Mifepristone has been approved by the FDA and remains the only drug approved in the United States for pregnancy termination. Since its approval, about three million women in the United States have used Mifepristone. And according to the FDA, this medication "has been increasingly used as its efficacy and safety have become well-established by both research and experience, and serious complications have proven rare."[3]

Despite Mifepristone's benefits and safety, the FDA subjects it to a REMS designation that is outdated, inconsistent with medical evidence, and limits healthcare providers' ability to use telehealth and provide this necessary drug, ultimately limiting patients' access to care. The Nation's leading reproductive healthcare specialists, the American College of Obstetricians and Gynecologists (ACOG), agree that the REMS are "outdated and substantially limit access to safe, effective medication," and have advocated for the FDA to remove the REMS.[4] Further, both the American Medical Association and American Academy of Family Physicians have also urged their removal.[5]

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[3] Mifepristone is used in a regimen with the drug misoprostol as a medical option for terminating an early pregnancy. The FDA has approved the use of this regimen through 70 days (i.e. 10 weeks of pregnancy). The patient first takes Mifepristone, in a single oral dose on day one. Then, 24-48 hours later, she takes the misoprostol. Most women experience a miscarriage within 2 to 24 hours after taking the misoprostol. The FDA label does not specify where the patient should be located when she takes either medication; however, the REMS requirements dictate that she be handed the Mifepristone (but not the misoprostol) at a clinic, medical office, or hospital under the supervision of a health care provider.

[4] Improving Access to Mifepristone for Reproductive Health Indications, ACOG (June 2018) https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/improving-access-to-mifepristone-for-reproductive-health-indications.

[5] "The AAFP seeks changes in the drug's current REMS designation to conform to current evidence. This aligns with other medical specialty organizations, such as the American College of Obstetricians and Gynecologists. Recent research also indicates the agency's safety protocols are particularly stringent for the drug. Most importantly, the current drug label creates an unnecessary health care barrier for women who need it the most." Letter to the FDA, AAFP (June 20, 2019), https://www.aafp.org/dam/AAFP/documents/advocacy/prevention/women/LT-FDA-MifepristoneREMS-062019.pdf; *Mifepristone*, AMA Policy (2018), https://policysearch.ama-assn.org/policyfinder/detail/mifepristone?uri=%2FAMADoc%2FHOD.xml-H-100.948.xml

Under the REMS, the FDA requires that (1) a patient be handed the Mifepristone at a clinic, medical office, or hospital under the supervision of a healthcare provider; (2) the healthcare provider must be registered with the drug manufacturer; and, (3) the patient must sign a "Patient Agreement" form confirming that she has received counseling on the risks associated with Mifepristone. These onerous and medically unnecessary requirements limit healthcare providers' ability to assist their female patients, particularly during this global healthcare crisis.

For example, due to the REMS, patients have to travel to a designated clinic, medical office, or hospital, as opposed to getting a prescription from their doctor using telehealth, and then obtaining Mifepristone at a local pharmacy or delivered by mail. The FDA should not mandate this medically unnecessary travel, particularly during the COVID-19 crisis where not only are women being advised to stay home, but families are faced with additional childcare and financial constraints.

The REMS also require that a prescriber must be registered with the manufacturer in order to prescribe Mifepristone, which poses additional obstacles. Once a prescriber is certified, the prescriber must set up an account with the drug distribution company, provide the distribution company with a hard copy of their U.S. DEA license and state medical license, and then sign a special resolution to become a Mifepristone dispenser. These steps create delays and obstacles to accessing care for women under even the best of circumstances. In this time of crisis, when the States are being encouraged to expand use of telehealth in order to bend the curve and contain the spread of COVID-19, these REMS barriers on Mifepristone mean that providers cannot increase access to meet demand.

Yet, the most burdensome aspect of the REMS are the "Elements to Assure Safe Use." These requirements must be "commensurate with the specific serious risk[s]" listed in the drug label, "required as part of [a] strategy to mitigate" such risks, and not be "unduly burdensome on patient access to the drug, considering in particular . . . patients in rural or medically underserved areas."[6] Mifepristone should not be subjected to these requirements when numerous medical studies have shown that Mifepristone is safe. In fact, Mifepristone is *four times* safer than Viagra and *fourteen times* safer than carrying a pregnancy to term. The FDA itself has stated that the "safety profile of Mifepristone is well-characterized and its risks well-understood after more than 15 years of marketing. Serious adverse events are rare and the safety profile of Mifepristone has not substantially changed." Furthermore, given the current pandemic, this requirement is imposing significant burdens on women in rural and medically underserved communities in accessing care, not to mention the additional burdens it imposes to all women across the country as the Centers for Disease Control and Prevention and the World Health Organization urge people to stay home.

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[6] 21 U.S.C. §§ 355-1(f)(1)(A), 2(A), 2(C).

In light of the unprecedented COVID-19 crisis, we request you remove the FDA's restrictive REMS designation for Mifepristone thereby removing these unnecessary, undue burdens in accessing safe and time-sensitive, essential medical care. Alternatively, at a minimum, we request that you use your enforcement discretion to allow certified prescribers to use telehealth for mifepristone. As you know, all residents of California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Minnesota, New Mexico, New York, North Carolina, Oregon, and Vermont are ordered to shelter-in-place or are under similar restrictions, as are other Americans around the country, and our economy is feeling those immediate impacts. National public health experts urge the same nationwide. However, with the FDA's REMS designation, women seeking to obtain healthcare cannot abide by such requirements. These women are putting themselves and their families at risk when they seek out the healthcare that they need, and the federal government must act to ensure that no matter where they live, they can continue to receive necessary, safe, and legal abortion care.

Sincerely,

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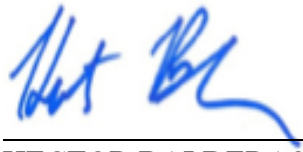

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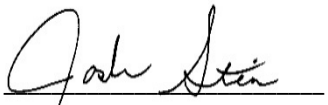

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